In the
United States Court of Appeals
For the Seventh Circuit

No. 04-2532

TED KELSO,

Plaintiff-Appellant,

v.

BAYER CORPORATION,

Defendant-Appellee.

Appeal from the United States District Court
for the Northern District of Illinois, Eastern Division.
No. 02 C 8601—**James F. Holderman**, *Judge.*

ARGUED DECEMBER 7, 2004—DECIDED FEBRUARY 18, 2005

Before BAUER, MANION, and WILLIAMS, *Circuit Judges.*

MANION, *Circuit Judge.* Ted Kelso sued Bayer Corporation for strict product liability, alleging that the warning Bayer provided on its Neo-Synephrine 12 Hour Extra Moisturizing Spray was defective. The district court granted Bayer summary judgment. Kelso appeals. We affirm.

I.

Ted Kelso began using Neo-Synephrine 12 Hour Extra Moisturizing Spray in 1990. He used Neo-Synephrine continuously for more than three years. After learning that his continued use of the product caused permanent nasal tissue

damage requiring multiple sinus surgeries, he sued Bayer, the manufacturer of Neo-Synephrine, alleging Bayer failed to adequately warn him of the dangers associated with Neo-Synephrine.

Bayer moved for summary judgment, arguing that the warning it provided, as follows, was adequate, as a matter of law:

> **"Do not exceed recommended dosage."**
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> *******
>
> **"Stop use and ask a doctor if symptoms persist. Do not use this product for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen."**

The district court agreed and granted Bayer summary judgment. Kelso appeals.

II.

On appeal, Kelso argues that the district court erred in granting Bayer summary judgment on his failure-to-warn claim. This court reviews a grant of summary judgment de novo. *Williams v. REP Corp.*, 302 F.3d 660, 662 (7th Cir. 2002). Summary judgment is appropriate if there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. *Id.* The parties agree that Illinois law governs this diversity action.

Kelso argues that summary judgment was inappropriate because he presented sufficient evidence to recover in a product liability action against Bayer. "To recover in a product liability action, a plaintiff must plead and prove that the injury resulted from a condition of the product, that the condition was an unreasonably dangerous one, and that the condition existed at the time the product left the manufacturer's control." *Sollami v. Eaton*, 772 N.E.2d 215,

219 (Ill. 2002). A product may be unreasonably dangerous because of a design defect, a manufacturing defect, "or a failure of a manufacturer to warn of a danger or instruct on the proper use of the product as to which the average consumer would not be aware." *Id.*

Kelso claims the Neo-Synephrine was unreasonably dangerous because Bayer's warning was confusing as to whether or not the product could be used safely for more than three days, when such use was effective in relieving his congestion. As Kelso explained in his affidavit, he interpreted the warning as meaning not to exceed three days use if the product failed to relieve the congestion; he only needed to see a physician if the product did not work to relieve the congestion. Also, because the container included much more than three days' dosage, Kelso insists that he had good reason to believe that he could safely use Neo-Synephrine for more than three days.

However, Kelso's personal reaction to the warning is not the test. Whether a warning is sufficient "is determined using an objective standard, i.e., the awareness of an ordinary person." *Klen v. Asahi Pool, Inc.*, 643 N.E.2d 1360, 1363 (Ill. App. Ct. 1994). *Id.* ("The duty to warn analysis, which is an objective one, should focus on the typical user's perception and knowledge."). Here, the plain, clear and unambiguous language of the warning states: **"Do not use this product for more than 3 days."** Period. That the Neo-Synephrine container included doses sufficient to treat multiple users or multiple colds in no way takes away from the clear impact of the warning. Moreover, the warning clearly informs users to: **"Stop use and ask a physician if symptoms persist."** The warning was clear. Yet Kelso continued using the product well beyond the three days. It is unreasonable to create an ambiguity that excuses extended use when the warning against such use is unequivocal.

Kelso also argues that the warning was inadequate because it did not warn users that the product could also cause permanent nasal tissue damage and also had a risk of habituation (meaning that users would become dependent on the product, causing them to use the product for more than three days). However, under Illinois law, a manufacturer need not warn of all possible consequences of failing to follow a primary warning. *Todd v. Societe BIC S.A.*, 9 F.3d 1216, 1218-19 (7th Cir. 1993). Here, the primary warning told consumers "**not [to] use this product for more than 3 days**." That was sufficient under Illinois law. However, Bayer's warning went even further, informing consumers of the consequence of extended use, stating: **"[f]requent or prolonged use may cause nasal congestion to recur or worsen."** Although Kelso believes the warning should have provided him with more detailed information, Illinois law does not require more. *Id.* Therefore, Kelso's defective warning claim fails.

Moreover, as Bayer points out, the Food and Drug Administration has issued a monograph that dictates the language that manufacturers must use for labeling topical nasal decongestants such as Neo-Synephrine. 59 Fed. Reg. 43386, 43396 (Aug. 23, 1994) ("All OTC drug labeling required by a monograph or other regulation (e.g., statement of identity, warnings, and directions), must appear in the specific wording established under the OTC drug monograph or other regulation where exact language has been established and identified by quotation marks . . . ."). Bayer maintains that because its warning, excerpted above, complied with the FDA-required warning, Kelso cannot challenge the adequacy of the warning.[1] For this added reason, we conclude that the

[1] The warning provided differed slightly from the current labeling (continued...)

warning provided was adequate as a matter of law.[2]

Kelso also seemingly presents a design defect claim, arguing that Neo-Synephrine was unreasonably dangerous because it contained benzalkonium chloride, which is an antimicrobial preservative used in nasal sprays so that bacteria will not grow in the product. Kelso argues that the warning would have been adequate had Bayer deleted the preservative, benzalkonium chloride, from the Neo-Synephrine, and that without this ingredient, Kelso would not have been injured. Kelso, however, failed to raise the issue of a design defect until his reply brief, and even then he failed to cite any legal support or develop any legal argument in support of his position. Therefore, Kelso has waived any claim of a design defect.[3] *See Wilson v. Giesen*, 956 F.2d 738, 741 (7th Cir. 1992) ("This argument is waived, however, as the plaintiff failed to raise it until his reply brief, leaving the defendants no chance to respond.");

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[1] (...continued)
requirements, in that it stated: "Stop use and ask a doctor if symptoms persist," at the beginning of the warning, whereas the current regulation requires the warning to end with the sentence: "If symptoms persist, consult a doctor." 59 Fed. Reg. at 43388. Bayer explained during oral argument that at the time it manufactured the product used by Kelso, the warning label complied with the FDA's specifications.

[2] Bayer does not argue that Kelso's warning defect claim is preempted by federal law because federal law specified the required warning. Because we conclude that the warning provided is adequate under Illinois law, we need not reach the question of preemption.

[3] Kelso also argues that Bayer mislabeled Neo-Synephrine by listing benzalkonium chloride as an inactive ingredient, when it was in fact an active ingredient. Bayer counters that the FDA has listed benzalkonium chloride as an inactive ingredient. However, because Kelso does not present a misrepresentation claim, whether benzalkonium chloride is active or inactive is irrelevant.

Thompson v. Boggs, 33 F.3d 847, 854 (7th Cir. 1994) ("[The appellant] has failed to develop his argument or cite any legal authority, thus, under our Circuit's precedent, the argument is waived.").

III.

Kelso used Neo-Synephrine for more than *three years*, resulting in permanent injury. However, because Bayer clearly and explicitly warned consumers not to use Neo-Synephrine for more than *three days*, Kelso's product liability claim for failure to warn fails. We AFFIRM.

A true Copy:

Teste:

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Clerk of the United States Court of Appeals for the Seventh Circuit